4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0710]

Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection; Draft Guidance for Industry, Revision 1; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled, "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection." The FDA Reauthorization Act of 2017 (FDARA) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) so that, as is the case with a drug, a device is deemed to be adulterated if the owner, operator, or agent of the factory, warehouse, or establishment at which the device is manufactured, processed, packed, or held delays, denies, or limits an FDA inspection. This draft guidance describes, for both drugs and now devices, the types of behaviors (actions, inactions, and circumstances) that the FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection. Once finalized, this draft guidance is intended to supersede the October 2014 FDA final guidance for industry entitled, "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection." However, until this draft guidance is finalized, the October 2014 FDA guidance remains in effect until it is withdrawn and will continue to reflect FDA's current thinking on this issue. FDA is particularly interested in comments on the inclusion of devices to the October 2014 guidance.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure

that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-D-0710 for "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for a single hard copy of the draft guidance to the Division of Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Drive, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lola Burford, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20857, Lola.Burford@fda.hhs.gov, 240-402-5865.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144) added section 501(j) to the FD&C Act (21 U.S.C. 351(j)) to deem adulterated a drug that "has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection." Section 707(b) of FDASIA required the Food and Drug Administration to issue guidance that defined the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of section 501(j) of the FD&C Act. In the *Federal Register* of October 22, 2014 (79 FR 63130), FDA announced the availability of a guidance for industry entitled, "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection" (hereinafter, 2014 guidance).

Subsequently, on August 18, 2017, FDARA (Pub. L. 115-52) was signed into law. Section 702 of FDARA amended the scope of section 501(j) of the FD&C Act to provide that, as the case with drugs, devices are deemed to be adulterated if an FDA inspection is delayed, denied, limited, or refused by the owner, operator, or agent of the establishment at which the

device is manufactured, processed, packed, or held. This draft guidance is intended to update the 2014 final guidance to incorporate devices and to explain the circumstances that FDA would consider to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, resulting in a drug or device manufactured in the facility being deemed adulterated. The 2014 guidance will remain in effect and will continue to reflect FDA's current thinking regarding circumstances that would constitute delaying, deny, or limiting inspection, or refusing to permit entry or inspection, for purposes of 501(j) of the FD&C Act with respect to drug inspections, until this draft guidance is finalized.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection" and will supersede the 2014 guidance. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/search-general-and-cross-cutting-topics-guidance-documents, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov. Persons unable to download an electronic copy of "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection" may send an email request to ORAPolicyStaffs@fda.hhs.gov to receive an electronic copy of the document.

Dated: December 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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